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I. FEDERAL RULE 26(C) AND LOCAL RULE 26.04(B) COMPLIANCE

Pursuant to Federal Rule of Civil Procedure 26(c) and Local Rule 26.04(b), Plaintiffs Takeda GmbH, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited (collectively, “Plaintiffs”) have in good faith conferred with Defendant Mylan Pharmaceuticals, Inc. (“Mylan”) via telephone to resolve this dispute without court intervention.

II. INTRODUCTION

As set forth in Plaintiffs’ pending motion to stay this action, Plaintiffs believe that this case should be stayed in its entirety in favor of an earlier filed suit against Mylan in the District of New Jersey, where nine other ANDA cases involving Plaintiffs’ Daliresp® pharmaceutical product and the patents-in-suit are pending. The present case was filed as a protective measure to preserve Plaintiffs’ statutory right to the thirty-month stay on FDA approval of Mylan’s ANDA under the Hatch-Waxman Act. Plaintiffs anticipate that the New Jersey cases will soon be consolidated or coordinated for pre-trial purposes, and a status conference to address that issue is currently scheduled for October 20, 2015.

Notwithstanding the pending motion to stay, on September 21, 2015, Mylan served on Plaintiffs 129 requests for production and eight interrogatories. Requiring Plaintiffs to respond to Mylan’s discovery requests before the Court even determines whether this case will proceed would result in inefficient and uncoordinated discovery across this case and the ten pending New Jersey actions. As Mylan itself has recognized, discovery in this case presents unique challenges, including that many of the named inventors of the patents-in-suit, and thus documents related to the inventions, reside in Germany. Accordingly, issues such as taking depositions of foreign witnesses, translating foreign-language documents, and establishing document redaction protocols in accordance with European Union and German privacy laws will need to be negotiated. Additionally, requests for depositions are likely to overlap across all cases, and witnesses—particularly those residing outside of the United States—should not be burdened by having to sit for duplicative depositions. Thus, in the interest of efficiency, and to avoid inconsistent outcomes on similar discovery issues, it makes sense for Plaintiffs and all ten

defendants to negotiate a plan for dealing with these issues at one time in the context of a consolidated action, rather than piecemeal.

Accordingly, Plaintiffs request that the Court issue a protective order relieving Plaintiffs of the obligation to respond to any discovery requests served by Mylan, at least until the Court has ruled on Plaintiffs' pending motion for a stay.

III. FACTUAL BACKGROUND

On May 15, 2015, Plaintiffs filed a patent infringement suit against Mylan in the District of New Jersey, where nine other suits involving the same drug product and patents are currently pending before Judge Freda Wolfson. *See Takeda GmbH v. Mylan Pharm., Inc.*, No. 3:15-cv-03384, Dkt. 1 (D.N.J. May 15, 2015) ("New Jersey Action"). The nine cases against the other defendants are well on their way to being consolidated for discovery purposes. The defendants have all answered the complaints in their respective cases, and, in response to Plaintiffs' letter concerning coordination or consolidation, Judge Wolfson entered an order assigning all ten cases to Magistrate Judge Arpert for pre-trial proceedings. *See Takeda GmbH v. Torrent Pharma Inc.*, No. 3:15-cv-03375, Dkt. 13 (D.N.J. July 28, 2015). A single status conference to discuss consolidation has been scheduled for October 20, 2015. *See id.*, Dkt. 27 (D.N.J. Sept. 24, 2015).

Correctly anticipating that Mylan would challenge jurisdiction in New Jersey, Plaintiffs also filed this action on May 27, 2015, as a protective measure in the unlikely event that Mylan prevails on its jurisdictional challenge, so as to preserve Plaintiffs' statutory thirty-month stay of FDA approval of Mylan's ANDA. *See* Dkt. 1. But, on June 26, 2015, Mylan answered Plaintiffs' complaint in this action before it was served and before answering the complaint in the first-filed New Jersey Action. *See* Dkt. 8. In response, on July 17, 2015, Plaintiffs filed an answer to Mylan's counterclaims and simultaneously moved to stay this case in its entirety pending the earlier of the resolution of (1) Mylan's motion to dismiss in the New Jersey Action, or (2) Mylan's jurisdictional Federal Circuit appeals in other cases. *See* Dkt. 13. Briefing on Plaintiffs' motion concluded on August 10. *See* Dkt. 21.

While Plaintiffs' motion was pending, the Court issued its order and notice regarding discovery and scheduling, ordering the parties to conduct their Rule 26(f) conference by September 21, 2015, before either party initiates discovery. *See* Dkt. 20. At the ensuing Rule 26(f) conference held on September 18, counsel for Plaintiffs conveyed Plaintiffs' position that discovery should not proceed in light of Plaintiffs' pending motion to stay, and that a case schedule should not be entered until the Court resolves that motion. *See* Dkt. 24 (Rule 26(f) Report) at 3, 7-8. Plaintiffs' counsel also raised the need for coordinated discovery across the related cases, particularly given the unique issues presented here, including those related to documents and witnesses residing in Germany. *Id.* at 3.

Rather than providing its own case scheduling position, Mylan served its first set of interrogatories and requests for production on September 21—the same day as the deadline for holding the Rule 26(f) conference—including 129 extremely broad and duplicative requests for production. *See* Ex. A (2015-09-21 Mylan's First Set of Reqs. for Prod.); Ex. B (2015-09-21 Mylan's First Set of Interrogs.).

IV. ARGUMENT

For the reasons stated in Plaintiffs' briefing in support of their motion to stay, *see* Dkts. 14, 21; *see also Landis v. N. Am. Co.*, 299 U.S. 248 (1936), this case should be stayed in its entirety—which includes staying discovery—in favor of the New Jersey Action. In addition, because Mylan has taken steps to begin discovery notwithstanding the pending request for a stay, a protective order relieving Plaintiffs of the obligation to respond to discovery requests is warranted, at least until the Court rules on the motion to stay.

Rule 26(c) provides that a “court may, for good cause, issue an order to protect a party or person from annoyance, . . . oppression, or undue burden or expense, including” by “forbidding the disclosure of discovery” outright, or “limiting the scope of disclosure or discovery to certain matters.” Fed. R. Civ. P. 26(c)(1)(A), (c)(1)(D); *see also* LR Civ. P. 26.05(a). It is well established that “Rule 26(c) vests the court with discretion to stay discovery.” *Rullan v. Goden*, 2014 WL 5464835, at *1 (D. Md. Oct. 27, 2014) (internal quotation marks omitted). Further, the Rule “confers broad discretion on the trial court to decide

when a protective order is appropriate and what degree of protection is required.” *Small v. Ramsey*, 280 F.R.D. 264, 269 (N.D.W. Va. 2012) (quoting *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984)).

Under this framework, a protective order is warranted here for two reasons.

First, a protective order would conserve judicial and party resources by “avoid[ing] the possibility that the parties will unnecessarily expend time and resources conducting discovery.” *IPVX Patent Holdings, Inc. v. 8X8, Inc.*, 2013 WL 6000590, at *2 (N.D. Cal. Nov. 12, 2013) (staying discovery under Rule 26(c) pending resolution of motion to disqualify plaintiff’s counsel). Courts routinely stay discovery in circumstances where, as here, motions having “the potential to significantly impact the nature and extent of further proceedings” are pending. *Ford v. Exelis, Inc.*, 2014 WL 2048182, at *3 (E.D.N.C. May 19, 2014) (using inherent power to stay entry of scheduling order and service of pre-discovery disclosures pending resolution of motion to dismiss for lack of subject matter jurisdiction). A stay in such cases “serve[s] ‘the interest of justice’ by conserving the time and resources of the parties and the court.” *Id.* Indeed, staying discovery pending the determination of whether a case will proceed is recognized as “an eminently logical means to prevent wasting the time and effort of all concerned, and to make the most efficient use of judicial resources.” *United States v. Daily Gazette Co.*, 2007 WL 7575700, at *2 (S.D.W. Va. Oct. 18, 2007) (internal quotations marks omitted) (staying discovery pending resolution of dispositive motion).

The parties currently await resolution of Plaintiffs’ motion to stay as well as the decision on Mylan’s jurisdictional motion in New Jersey, which both have the potential to significantly alter the landscape of this case. A protective order relieving Plaintiffs of the need to respond to Mylan’s discovery requests until that time would allow Plaintiffs to avoid needlessly expending resources and money responding to Mylan’s interrogatories and 129 requests for production, and preparing to produce documents in response thereto.

Second, a protective order would allow for a coordinated resolution to the unique discovery issues presented in the multiple cases involving the patents-in-suit. See *Samson Resources Co. v. J. Aron & Co.*, 2009 WL 1606564, at *2 (N.D. Okla. June 8, 2009) (finding good cause to stay discovery where

there was “the *potential* for inconsistencies in discovery and case management between” two co-pending cases involving the same parties (emphasis in original)); *Intervet, Inc. v. Merial Ltd.*, 655 F. Supp. 2d 131, 134-35 (D.D.C. 2009) (noting that, “[f]or purposes of efficiency, a single court should oversee discovery relevant to the” patent-in-suit). As discussed above, nine other cases involving nine other defendant groups have been assigned to a single magistrate judge in the District of New Jersey, and Plaintiffs expect that those cases will soon be consolidated at least for purposes of discovery. These cases require careful consideration of how discovery will proceed in light of the unique issues in this case.

For example, many of the named inventors of the patents-in-suit reside in Germany, where relevant documents concerning the inventions also are located. These documents may require translation and must also be reviewed and potentially redacted in accordance with European Union and/or German privacy laws, as Mylan itself recognized after serving its discovery requests. *See* Ex. C (2015-09-23 Letter from Mr. Gregory to Ms. Wigmore); Dkt. 24 (Rule 26(f) Report) at 3, 5, 6-8. In addition, depositions of witnesses, particularly those located outside the United States, should be coordinated such that they need not be deposed on the same issues multiple times. In light of these unique factors, it is important that discovery proceed in a coordinated fashion.

Further, while Mylan’s 129 requests for production and eight interrogatories are redundant, overly broad, and objectionable for a variety of other reasons, Plaintiffs expect that requests covering the same or similar subject matter will be served in the New Jersey actions. Thus, proceeding with discovery now, while Plaintiffs’ motion is pending, will result in two strands of overlapping discovery, in which outcomes on disputed issues may differ—a result that is inefficient and wasteful, and can easily be avoided by imposing a limited stay of discovery in this case. *Precision Biosciences, Inc. v. Cellectis S.A.*, 2011 WL 6001623, at *2 (E.D.N.C. Nov. 30, 2011) (noting that, because the parties were “proceeding with discovery in the” first-filed action, “absent a stay, duplicative litigation will result”); *Samson Resources*, 2009 WL 1606564, at *2 (staying discovery in case that would require “extensive . . . discovery rulings” on complex issues, “all of which may be avoided in the event the litigation is . . . transferred” to another forum).

Thus, good cause exists to enter a protective order relieving Plaintiffs of the obligation to respond to discovery requests pending the resolution of Plaintiffs' motion to stay.

V. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that its motion for a protective order be granted.

Dated: October 9, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of October, 2015, I electronically filed the foregoing
**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR A PROTECTIVE ORDER
RELIEVING THEM OF THE OBLIGATION TO RESPOND TO DISCOVERY UNTIL
RESOLUTION OF PLAINTIFFS' MOTION TO STAY** with the clerk of the Court by using the
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